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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,117	10/13/2005	Francois-Xavier Berthet	B45315	8407

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SMITHKLINE BEECHAM CORPORATION
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EXAMINER

MAASHO, KERIMA K

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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10/19/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/523,117	Applicant(s) BERTHET ET AL.	
	Examiner Kerima Maasho	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-60, 61, 82-91, drawn to an immunogenic composition comprising antigens.

Group II, claim(s) 62, drawn to a vaccine comprising polynucleotides.

Group III, claim(s) 63-68, 80-81, drawn to a method of treatment or prevention.

Group IV, claim(s) 69-76, drawn to a method of making an immunogenic composition.

Group V, claim(s) 77-79, drawn to a method of preparing an immune globulin.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed inventions are drawn to an immunogenic composition and vaccines for the treatment of Neisserial disease. The claimed immunogenic composition comprising of two or more different antigens selected from a) at least one Neisserial adhesin; b) at least one Neisserial autotransporter; at least one Neisserial toxin; at least one Neisserial Fe acquisition protein; or at least one Neisserial membrane associated protein, preferably integral outer membrane protein. The technical feature of groups I and IV are not special in view of the teachings of Robinson et al (WO/00/25811, filed in the IDS). Robinson et al disclose a multicomponent meningococcal vaccine comprising transferring binding proteins A and B (TbpA and TbpB) with other components such as Neisserial outer membrane vesicles and Cu, Zn-superoxide dismutase. Robinson et al

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also teach methods for preparation of these compositions and their uses in vaccination against meningococcal disease.

As such groups I-V drawn to the above immunogenic compositions and methods of treatment and methods of making lack unity of invention because the technical feature of groups I and IV are not "special" in that they do not define a novel contribution over the prior art.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicants must elect a single species from the following groups 1-8

1) Neisserial adhesin is:

Species: A) FhaB, B) NspA, C) PilC, D) Hsf, E) Hap, F) MafA, G) MafB, H) Omp26, I) NMBO315, J) NMB0995, K) NMB 1119 L) NadA,
as stated in claims 2, 4, 6, 8, 10, 13, 16-44, 62

2) Neisserial autotransporter:

Species: A) Hsf, B) Hap, C) IgA protease, D) AspA E) NadA
as stated in claims 2, 4, 6, 8, 10, 13, 16-44, 62

3) Neisserial toxin:

Species: A) FrpA, B) FrpC, C) FrpA/C, D) VapD, E) NM-ADPRT, F) LPS immunotype L2, G) LPS immunotype L3
as stated in claims 2, 4, 6, 8, 10, 13, 16-44, 62

4) Neisserial Fe acquisition:

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Species: A) TbpA high, B) TbpA low, C) TbpB high, D) TbpB low, E) LbpA, F) LbpB, G) P2086, H) HpuA, I) HpuB, J) Lipo28, K) Sibp, L) FbpA, M) BfrA, N) BfrB, O) Bcp, P) NMB0964, Q) NMB0293

as stated in claims 2, 4, 6, 8, 10, 13, 16-44, 62

5) Neisserial membrane associated protein:

Species: A) PilQ, B) OMP85, C) FhaC, D) NspA, E) TbpA(high), F) TbpA(low), G) LbpA, H) HpuB, I) TspA, J) TspB, K) TdfH, L) PorB, M) HimD, N) HisD, O) GNA1870, P) OstA, Q) HlpA, R) MltA, S) NMB 1124, T) NMB 1162, U) NMB 1220, V) NMB 1313, W) NMB 1953, X) HtrA, Y) PldA

as stated in claims 2, 4, 6, 8, 10, 13, 16-44, 62

6) Genes to down regulate:

Species: A) ItgB, B) ItgE, C) siaD, D) ctrA, E) ctrB, F) ctrC, G) ctrD, H) synA, I) synx, J) siaA, K) synB, L) siaB, M) sync, N) siaC, O) OpC, P) OpA, Q) PorA, R) frpB, S) msbB, T) htrB

as stated in claims 45-49, 91

7) Antigen derived from: (and Infection is:)

Species A: *Neisseria meningitidis*

Species B: *Neisseria gonorrhoeae*

as stated in claims 52, 53, 64, 65, 67, 68

8) Bacterial capsular polysaccharide/oligosaccharide derived from:

Species A: *Neisseria meningitidis*

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Species B: *Haemophilus influenzae* b

Species C: *Streptococcus pneumoniae*

Species D: Group A *Streptococci*

Species E: Group B *Streptococci*

Species F: *Staphylococcus aureus*

Species G: *Staphylococcus epidermidis*.

as stated in claims 56

Applicants must further elect a single species of *N. meningitidis* serotype

Species A: serogroup A

Species B: serogroup B

Species C: serogroup C

Species D: serogroup Y

Species E: serogroup W-135

as stated in claims 52, 56

The following claim(s) are generic: claims 1, 3, 5, 7, 9, 61, 63, 66, 69-72, 76-77, 79-81.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The antigen proteins of groups 1-5 have different composition, specificities and functional properties as exemplified by their names. For example, adhesins are involved in the binding of *Neisseria* to the surface of host cells and iron acquisition proteins are involved in the trafficking of iron via the outer membrane receptor protein complex. Structure wise, autotransporter proteins typically are made up of a signal sequence, a passenger domain and an anchoring domain for attachment to the outer membrane.

The different genes of group 6 have different functional properties for example while the *lgtB* gene deletion results in the inhibition of capsular polysaccharide production, while deletion of *siaD* gene results in the downregulation of the α -2-8 polysialyltransferase activity.

The *Neisseria* strains of group 7 *N. meningitidis* and *N. gonorrhoeae* cause different diseases and have different ways of transmission, moreover they have specific genes that do not overlap that could be involved in the pathogenesis of the organisms.

The bacterial species of group 8 belong to different bacterial families and have different characteristics and manifest different clinical infections.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

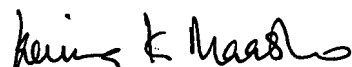
Claims 1-91 are subject to restriction and species election as explained above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kerima Maasho whose telephone number is 571-270-3055. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



/Kerima Maasho/

Patent Examiner, Art Unit 1645



JEFFREY SIEW
SUPERVISORY PATENT EXAMINER